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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,979	05/10/2000	THOMAS J. HIGGINS	33-00	4903

23713            7590            03/14/2002

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5370 MANHATTAN CIRCLE  
SUITE 201  
BOULDER, CO 80303

[REDACTED] EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	B

DATE MAILED: 03/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/508,979	HIGGINS ET AL.
	Examiner Cynthia Collins	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 January 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2,4-6,8,11-57,64,65,67-69,86-94 and 96-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4-6,8,11-57,64,65,67-69,86-94,96-100 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

The Amendment filed December 19, 2001, paper no. 11, has been entered.

The formal drawings filed December 19, 2001, paper no. 12, have been entered.

Claims 3, 7, 9, 10, 58-63, 66, 82-85 and 95 have been cancelled.

Claims 1, 4-6, 8, 11, 14, 16-17, 19-21, 24, 27-28, 33, 37-38, 42, 47, 52, 64-65, 67-69, 86-94, 96 and 99-100 have been newly amended.

Claims 1-2, 4-6, 8, 11-57, 64-65, 67-69 and 86-94 and 96-100 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

The objection to claim 100 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, is withdrawn in light of Applicant's amendment of claim 100.

### ***Claim Rejections - 35 USC § 112 and 35 USC § 101***

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "and/or" is withdrawn in light of Applicant's amendment of claim 1.

The rejection of claims 1, 42, 47, and 52 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the phrase "at least" to modify "comprising" is withdrawn in light of Applicant's amendment of claims 1, 42, 47 and 52.

The rejection of claims 3 and 68 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the transitional phrase "comprising" preceding a Markush group is withdrawn in light of Applicant's amendment of claim 68 and cancellation of claim 3.

The rejection of claims 4 and 37 under 35 U.S.C. 112, second paragraph, as being indefinite because they are unduly alternative is withdrawn in light of Applicant's amendment of claims 4 and 37.

The rejection of claim 42 as being indefinite in the recitation of the phrase "modified composition of any amino acid" is withdrawn in light of Applicant's amendment of claim 1.

The rejection of claims 83-85 under 35 U.S.C. 112, second paragraph, as being indefinite in merely reciting a use without any active, positive steps is withdrawn in light of Applicant's cancellation of claims 83-85.

The rejection of claims 83-85 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process is withdrawn in light of Applicant's cancellation of claims 83-85.

The rejection of claims 86-87 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "storage organ" without sufficient antecedent basis is withdrawn in light of Applicant's amendment of claims 86-87.

The rejection of claim 88 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the phrase "total content of the seed" is withdrawn in light of Applicant's amendment of claim 88.

The rejection of claims 88 and 89 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the phrase "does not only increase the sulfurous content of the seed" is withdrawn in light of Applicant's amendment of claims 88 and 89.

The rejection of claims 96 and 99 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "genetic construct" without sufficient antecedent basis is withdrawn in light of Applicant's amendment of claims 96 and 99.

***Claim Rejections - 35 USC § 102***

The rejection of claims 1-16, 20-23, 28-31, 33-40, 42-44, 47-50, 52-65, 67-69, 83-85, 88-97, and 99-100 under 35 U.S.C. 102(b) as being anticipated by Molvig et al. (August 1997, Proc. Natl. Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicant's IDS) is withdrawn in light of Applicant's amendment of the claims to recite a process step that is not specifically taught by Molvig et al., the step of "determining the content or composition, or content and composition, of a metabolite in the storage organ, said metabolite selected from the group consisting of oil (fatty acid), starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fibre and protein nitrogen".

The rejection of claims 1-11, 13-14, 20, 65, 67-69, and 83-85 under 35 U.S.C. 102(b) as being anticipated by WO 95/27068 (12 October 1995, Applicant's IDS) is withdrawn in light of

Applicant's amendment of the claims to eliminate the recitation of "endogenous anti-nutritional factors", and to recite a process step that is not specifically taught by Molvig et al., the step of "determining the content or composition, or content and composition, of a metabolite in the storage organ, said metabolite selected from the group consisting of oil (fatty acid), starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fibre and protein nitrogen".

***Claim Rejections - 35 USC § 103***

Claims 1-2, 4-6, 8, 11-57, 64-65, 67-69 and 86-94 and 96-100 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Molvig et al. (August 1997, Proc. Natl. Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicant's IDS).

Applicant argues that the content and/or composition of specific metabolites such as fatty acids, starch or fibre are not determined in the Molvig et al. disclosure, and that the Molvig et al. disclosure would not have motivated one of ordinary skill in the art at the time the invention was made to modify and subsequently determine the content and/or composition of these specific metabolites. Applicant also argues that the amendment of claim 1 to recite the modification and determination of "protein nitrogen" distinguishes the instant invention from Molvig et al. who determined total nitrogen in seed, which Applicant asserts does not accurately reflect seed protein content, and that in view of the distinction presented concerning nitrogen content versus protein content, the Patent Office has erred in concluding that it would have been obvious to substitute the noted types of plants.

Applicant's arguments have been fully considered but are not persuasive.

The Examiner maintains that although the content and/or composition of specific metabolites such as fatty acids, starch or fibre are not determined in the Molvig et al. disclosure,

these features of the claimed invention must be inherently present because practicing the claimed invention does not require additional method steps or the use of additional method components to achieve the desired effect before the determination of the content or composition, or content and composition, of a metabolite is made. The Examiner also maintains that the Molvig et al. disclosure would have motivated one of ordinary skill in the art at the time the invention was made to modify and subsequently determine the content and/or composition of these specific metabolites, because, to account for an unexpected increase in the palatability of transgenic seed, Molvig et al. teach that the expression of a chimeric gene that encodes a sulfur-rich protein may alter the synthesis of key catalytic or other regulatory proteins involved in other metabolic pathways, leading to other changes in seed components (page 8397, column 2, first full paragraph). Furthermore, Applicant's amendment of the claims to recite a process step that is not specifically taught by Molvig et al. does not make the claimed invention nonobvious in light of Molvig. et al., as methods for determining the content or composition, or content and composition, of a metabolite in the storage organ were known in the art at the time of Applicant's invention.

Additionally, the Examiner maintains that Applicant's amendment of claim 1 to recite the modification and determination of "protein nitrogen" does not make the claimed invention nonobvious in light of Molvig. et al. First, even though the content and/or composition of protein nitrogen was not determined in the Molvig et al. disclosure, this feature of the claimed invention must be inherently present in Molvig et al. because practicing the claimed invention does not require method steps or components other than those taught by Molvig et al. to achieve the desired effect before the determination of protein nitrogen is made. Second, although total nitrogen may not accurately reflect seed protein content, this is not always the case. Example 2

of the instant disclosure asserts that, in the case of transgenic peas containing SSA, "Seed nitrogen is mostly in the form of protein, therefore, it can be assumed that increased seed nitrogen equates to increased seed protein" (page 29, lines 27-28). Direct testing of this assumption confirmed that the increase in seed nitrogen observed in peas reflected an increase in seed protein (page 29 line 28 through page 30 line 3). Since practicing the claimed invention does not require method steps or components other than those taught by Molvig et al. to achieve the desired effect before the determination of protein nitrogen is made, the Examiner concludes that the levels of total nitrogen determined by Molvig et al. must accurately reflect seed protein content. Third, the claimed invention is not limited to modification of protein nitrogen, and Molvig et al. teach or suggest the modification of the content or composition of other metabolites, as discussed *supra*. Furthermore, since total nitrogen may accurately reflect seed protein content, and since the claimed invention is not limited to modification of protein nitrogen, the Examiner maintains that the Patent Office has not erred in concluding that it would have been obvious to substitute the noted types of plants.

Accordingly, Applicant's arguments are not persuasive.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
March 12, 2002

ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600

